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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,361	06/30/2000	Yasushi Shigemori	032735-003	9813
21839	7590	11/20/2003	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			MARVICH, MARIA	
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ALEXANDRIA, VA 22313-1404			PAPER NUMBER	

1636

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/607,361	Applicant(s) SHIGEMORI ET AL.	
	Examiner Maria B Marvich, PhD	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-14 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7, 9, 12, 13, 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 2, 5, 6, 8, 14 and 21 is/are rejected.
- 7) ☒ Claim(s) 3, 4 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some    \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/18/03
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This office action is in response to a Request for Continued Examination (RCE) and an amendment filed 10/8/2003. Claims 10-11 and 15-20 have been canceled. Claims 23-24 have been added and claims 1, 6 and 21 have been amended. Claims 1-9, 12-14 and 21-24 are pending. An IDS filed 6/18/2003 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

#### ***Claim Objections***

Claims 21 and 24 are objected to because of the following informalities: Claim 21, line 3 recites "a" prior to the plural "single stranded regions". In claim 24, "double-stranded" requires an article and, "no" is misspelled as "nots" in claim 24, line 2. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5-6, 8, 14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said three-stranded DNA structural complex" in claim 1. There is insufficient antecedent basis for this limitation in the claim. It would be remedial to recite, "said three-stranded structure".

Claim 2 is unclear for reciting that the three-stranded structure is made by ligation of a) and b) or c) and d) yet d) recites that the double-stranded nucleotide region is homologous to the single-stranded nucleotide region in a). As the sequences ligate due to homology between ends, the homology should be between the nucleotide regions in c) and d) not c) and a).

Claim 6 recites the limitation "the other DNA" in claim 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 is vague and indefinite in that the metes and bounds of a method of claim 1 "further comprises steps of converting the three-stranded structure into a double-stranded structure" are unclear. It is unclear as to the timing of these steps as they appear to be in place of the steps listed in step b of claim 1 as opposed to in addition.

Claim 21 recites the limitation "the sequence of a gene to be cloned" in claim 5. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 8 recites a method of ligation that comprises use of a homologous recombinant protein that is selected from the group consisting of Rec A or proteins that are functionally similar to the Rec A protein.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants teach the homologous recombinant protein can be Rec A protein from *E. coli* or proteins encoded by the *rec A* gene in heat-resistant bacteria or enteric bacteria (page 8, line 28-34). As well, applicants state that the already well-known Rec-A like proteins of several microorganisms, yeast and human are also encompassed by the invention. However, there is no disclosure as to the relative properties of a protein that is functionally similar to Rec A protein except the disclosure that the proteins “form a complex comprising the aforementioned three-stranded DNA portion” (page 9, line 2-8). But this disclosure is not accompanied by a description as to the relevant characteristics that are required from a protein that is functionally similar to Rec A. Therefore, there is no clear description of the structural or functional characteristics of a protein that is functionally similar to Rec A. Given the large size and diversity of proteins encompassed by the recited claims and the inability to determine which is also functionally similar to Rec A, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of

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one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

*Conclusion*

Claims 2, 5-6, 8, 14 and 21 are rejected.

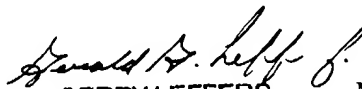
Claims 3-4 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 7, 9, 12-13 and 23-24 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**GERRY LEFFERS**  
**PRIMARY EXAMINER**

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

November 13, 2003